

REMARKS

Claims 19-27 have been examined. Claims 19, 22, and 23 have been amended. Claims 10-18 and 28-34 have been canceled. Claims 35-46 have been added. Re-examination and reconsideration of pending claims 19-27 and 35-46, as amended, are respectfully requested.

Restriction Requirement

Claims 10-18 and 28-34 have been canceled without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed application.

Rejection Under 35 U.S.C. § 102

Claims 19, 20, 23, 24, 26, and 27 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,505,730 issued to Edwards. Claims 19-22 and 24-27 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,283,961 issued to Underwood et al. Claims 19-22 and 24-27 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,035,238 issued to Ingle et al. Such rejections are now moot as described below.

To expedite prosecution of this case and more clearly claim the present invention, Applicants have amended claim 19 to recite a device for effecting a desired contraction of a discrete target region of a tissue so as to treat incontinence, the target region having a target region size and shape. The device of claim 19 now recites a probe having a treatment surface, the treatment surface size and shape corresponding to the size and shape of the target region and having a length of at least 10 mm and width of at least 5 mm. Further, at least one element is disposed along the treatment surface for transmitting energy from the treatment surface to the target region without moving the probe such that the energy effects the desired contraction of the target tissue without

ablating the target tissue, and so that the contracted target tissue inhibits the incontinence.

Such elements have not been shown.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. § 102. M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the claims." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The cited art references are clearly distinguishable from claim 19 in various aspects.

The Edwards reference describes a thin layer ablation apparatus comprising a balloon (12) having a conforming member (32) with a printed circuit (40) on a conductive surface (34) of the conforming member. This structure is specifically designed to apply RF ablation energy to an inner layer of an organ in the body, particularly an endometrium of a uterus to treat menorrhagia (i.e., excessive menstrual bleeding). See Figs. 2B and 3; col. 1, lines 6-9. The Underwood et al. patent describes a planar ablation probe (404) having a plurality of electrodes (416) for applying ablative RF energy to spinal tissue for treating herniated discs. See Figs. 20 and 21B; col. 1, lines 45-49; col. 28, lines 62-65. In contrast, the presently claimed device provides a static urinary incontinence device that contracts the target tissue without ablating the target tissue and so that the contracted target tissue inhibits the incontinence. This revolutionary and potentially non-invasive treatment device for urinary stress incontinence recited by claim 19 is not disclosed or suggested in either the Edwards or Underwood et al. references.

Moreover, the treatment surface having a length of at least 10 mm and a width of at least 5 mm is advantageous over the Edwards reference, which fails to remotely teach or suggest such an element, and the Underwood et al. reference, which recites that the electrodes (416) extend from a spacer (418) preferably less than 10 mm and have a width preferably between 2 mm and 4 mm. See Underwood et al. col. 29, lines 1-20. Specifically, the distinct probe treatment surface of claim 19 often sets the tissue heating pattern, as the probe will be held at a fixed position against tissue during

tissue heating. This predetermined heating pattern helps avoid over treatment of some tissues (e.g., ablation) and under contraction of others, as can occur when manually painting a small treatment surface repeatedly across the target tissue.

The Examiner contends that Ingle et al. shows a surface within the "size range set forth in the application claims". Office Action dated July 10, 2002, page 4. Applicants request, if the present rejection is maintained, that the Examiner show or explain where the Ingle et al. reference teaches or suggest the distinct structural limitation of a probe treatment surface having a length of at least 10 mm and a width of at least 5 mm, as presently claimed in claim 19.

"Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Absent a showing in a single prior art reference for a static urinary stress incontinence device comprising a probe having a treatment surface length of at least 10 mm and width of at least 5 mm and at least one energy transmitting element that contracts the target tissue without ablating the target tissue and so that the contracted target tissue inhibits the incontinence, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejections and allowance of independent claim 19 (and dependent claims 20-27 and 35-41).

Double Patenting

Claims 19-27 have been provisionally rejected under the judicially created non-statutory obviousness-type double patenting rejection over claims 2-4 of co-pending U.S. Patent Application No. 09/636,795. Applicants will address this rejection when this application is otherwise in condition for allowance.

Added Claims

Applicants have added claims 35-46 more fully claim the present invention. Support for these new claims can be found throughout the originally filed application. In particular, support for claims 35 and 46 can be found at page 13, lines 25-29; claims 36-38 and 45 at page 12, line 25 through page 13, line 5; claims 39-41 at page 23, line 12 through page 24, line 13; claim 42-44 at page 11, lines 7-20.

New dependent claims 35-41 should be allowable as they depend from independent claim 19. New independent claim 42 is directed at a static incontinence device comprising a probe body having a treatment surface length in a range from 10 mm to 50 mm and a width in a range from 5 mm to 30 mm and at least two electrodes transmitting bipolar energy such that the energy heat the target tissue so as to inhibit the incontinence. As such claim 42 (and dependent claims 43-46) should be allowable for many of the reasons given above with respect to claim 19.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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APPENDIX B
VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please cancel claims 10-18.

19. (Amended) A device for effecting a desired contraction of a discrete target region of a tissue so as to treat incontinence, the target region having a target region size and shape, the device comprising:

a probe having a treatment surface, the treatment surface size and shape corresponding to the size and shape of the target region and having a length of at least 10 mm and a width of at least 5 mm; and

at least one element disposed along the treatment surface for transmitting energy from the treatment surface to the target region without moving the probe such that the energy effects the desired contraction of the target tissue without ablating the target tissue, and so that the contracted target tissue inhibits the incontinence.

22. (Amended) The device of claim 19 [20], further comprising a thin flat probe body defining the treatment surface, wherein the treatment surface is at least semi-rigid.

23. (Amended) The device of claim 19 [20], wherein the probe body has an expansion member for urging the at least one element [electrodes] against the target tissue.

Please cancel claims 28-34.

35. (New) The device of claim 19, wherein the at least one element comprises a pair of elongate electrodes.

36. (New) The device of claim 35, wherein the electrodes transmit bipolar electrical energy to the target region.

37. (New) The device of claim 35, further comprising control means coupled to the electrodes for controlling the transmitted energy so that the target region is heated to a temperature in a range from about 70 °C to about 140 °C.

38. (New) The device of claim 35, wherein the electrodes are separated by a separation distance in a range from about 1 to about 10 times a radius of curvature of the electrodes.

39. (New) The device of claim 19, wherein the at least one element has a mechanism that limits transmitted energy so as to avoid ablation of the target tissue.

40. (New) The probe of claim 38, wherein the limit mechanism comprises a thermal mass, the at least one element comprising a heat transfer surface thermally coupled to the thermal mass, the thermal mass transferring a significant portion of the energy when the heat transfer surface cools from a safe tissue temperature toward body temperature.

41. (New) The probe of claim 38, wherein the limit mechanism comprises a reaction mass that reacts to transfer the energy and which is depleted when the energy is transferred.

42. (New) A device for heating a target fascial tissue so as to treat incontinence, the target tissue having a fascial surface, the device comprising:
a probe body having a treatment surface, the treatment surface being oriented for engaging the fascial surface, the probe body having a length in a range from about 10 mm to about 50 mm and a width in a range from about 5 mm to about 30 mm;
and

at least two electrodes disposed over the treatment surface for transmitting bipolar electrical energy into the engaged target tissue without moving the probe such that the energy heats the target tissue so as inhibit the incontinence.

43. (New) The device of claim 41, wherein the probe body comprises a thin flat structure, the treatment surface defining a major surface of the probe body.
44. (New) The device of claim 41, wherein the probe body is semi-rigid or rigid.
45. (New) The device of claim 41, further comprising a power source coupled to the electrodes via circuitry that delivers sufficient bipolar electrical power through the electrodes to the target tissue to effect heating of the target tissue without charring and without ablating the tissue.
46. (New) The device of claim 41, wherein the electrodes have an elongate shape.